BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0483; FRL-9923-59]

Dimethomorph; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of dimethomorph in or on papaya at 1.5 parts per million (ppm). BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) to cover residues of dimethomorph in papaya imported into the United States; there are currently no U.S. registrations for pesticides containing dimethomorph that are used on papaya.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0483, is available at *http://www.regulations.gov* or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices*@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0483 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0483, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8218) by BASF Corporation, P.O. Box, 13528, Research Triangle Park, North Carolina 27709. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide dimethomorph, in or on papaya at 1.5 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. No comments were received on the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dimethomorph including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dimethomorph follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Dimethomorph has low acute toxicity by the oral, dermal, or inhalation route of exposure. It is not an eye or skin irritant, and is not a skin sensitizer. There is no evidence that

dimethomorph is a developmental, reproductive, carcinogenic, mutagenic or immunotoxic chemical. Dimethomorph is classified as "not likely to be carcinogenic to humans" based upon lack of evidence of carcinogenicity in rats and mice.

No biologically significant effect was observed in the rat subchronic oral toxicity study while decreased body weight and increased incidence of arteritis in male rats and decreased body weights and increased incidence of “ground-glass” foci in livers of female rats were observed in the rat chronic toxicity study. In the dog subchronic oral toxicity study, decreased absolute and relative prostate weights, and slight liver effects were observed. No toxicity was observed at the limit dose in the rat 28-day dermal toxicity study. The developmental toxicity studies showed no increased sensitivity to offspring of either rats or rabbits as demonstrated by no-observed-adverse-effect-level’s (NOAEL) equal to or higher than those producing toxicity in the maternal animals. Likewise, in the 2-generation reproduction study, there was no toxicity to the offspring at doses lower than that causing parental toxicity.

In an acute neurotoxicity study, functional observational battery (FOB) findings and reduced motor activity were observed. However, these findings were considered an impairment of the overall condition of the animals following treatment, rather than direct neurotoxic effects of the dimethomorph exposure. No neurotoxic effects were observed in the subchronic neurotoxicity study in rats and there is no evidence of neurotoxicity throughout the dimethomorph toxicity database. There was no evidence of immunotoxicity in the immunotoxicity study.

Specific information on the studies received and the nature of the adverse effects caused by dimethomorph as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document

Dimethomorph: Human Health Risk Assessment to Support Establishment of a Tolerance Without U.S. Registration for Papaya on page 9 within the docket ID number EPA-HQ-OPP-2014-0483.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL at which adverse effects of concern are identified. Uncertainty/safety factors (U/SF) are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for dimethomorph used for human risk assessment is shown in the Table of this unit.

Table --Summary of Toxicological Doses and Endpoints for Dimethomorph for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and	RfD, PAD, LOC	Study and Toxicological

	Uncertainty/Safety Factors	for Risk Assessment	Effects
Acute dietary (Females 13-49 years of age)	No appropriate endpoint was identified including developmental toxicity studies in rats and rabbits.	Not applicable.	No study selected.
Acute dietary (General population)	LOAEL = 250 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF_L = 10x	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Acute Neurotoxicity Study LOAEL = 250 mg/kg/day based on reduced motor activity in both sexes.
Chronic dietary (All populations)	NOAEL= 11 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day cPAD = 0.1 mg/kg/day	Carcinogenicity study in rats LOAEL = 46.3 mg/kg/day based on decreased body weight and increases in liver lesions in female rats.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely" to be a human carcinogen.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to dimethomorph, EPA considered exposure under the petitioned-for tolerances as well as all

existing dimethomorph tolerances in 40 CFR 180.493. EPA assessed dietary exposures from dimethomorph in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for dimethomorph. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, EPA made the following assumptions for the acute exposure assessment: tolerance-level residues for all commodities, 100 percent crop treated (PCT) for all commodities and Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors or empirical processing factors.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's (NHANES/WWEIA) conducted from 2003-2008 as well. As to residue levels in food, EPA made the following assumptions for the chronic exposure assessment: Tolerance-level residues for all commodities, 100 PCT for all commodities and DEEM (ver. 7.81) default processing factors or empirical processing factors.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that dimethomorph should be classified as "not likely" to be a human carcinogen based upon lack of evidence of carcinogenicity in rats and mice. Therefore a cancer risk assessment was not necessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for dimethomorph. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The drinking water concentrations have not changed since the last assessment. The Agency utilized a maximum application rate of 1.4 pound active ingredient/acre/season (lb ai/A/season) for broccoli (which is the use with the most exposure and highest PCT area). The groundwater value was generated using the Screening Concentration in Groundwater (SCI-GROW) Model and the surface water values were generated using a Tier 1 broccoli model. The surface water estimate was used for both acute and chronic assessment (81.1 parts per billion (ppb) for acute and 24.7 ppb for chronic) because these values were higher than the groundwater value. Since the current petition is for a tolerance in/on imported papaya, an assessment of the impacts of that use on drinking water was not required.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dimethomorph is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found dimethomorph to share a common mechanism of toxicity with any other substances, and dimethomorph does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dimethomorph does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The available data did not provide evidence of increased sensitivity in the offspring based on the results from developmental studies conducted with rats and rabbits as well as a 2-generation reproduction study conducted with rats. There were no toxic effects observed in either the rat developmental toxicity or the rat 2-generation reproductive toxicity studies at doses that were lower than doses which produced toxic effects in the parents. Additionally, no developmental toxicity was demonstrated in the rabbit developmental toxicity study.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for dimethomorph is complete.

ii. The available data do not support a determination that dimethomorph is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that dimethomorph results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The unrefined acute and chronic dietary risk assessments used tolerance level residues, included modeled drinking water estimates, assumed 100 PCT, and incorporated DEEM default processing factors. EPA made conservative (protective) assumptions in the groundwater and surface water modeling used to assess exposure to dimethomorph in drinking water. These assessments will not underestimate the exposure and risks posed by dimethomorph.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dimethomorph will occupy 39% of the aPAD for children 3-5 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dimethomorph from food and water will utilize 25% of the cPAD for children 1-2 years the population group receiving the greatest exposure. There are no residential uses for dimethomorph.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, dimethomorph is not expected to pose a short-term risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however**,** dimethomorph is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for dimethomorph**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dimethomorph is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to dimethomorph residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

FAMS-002-04 which utilizes high performance liquid chromatography with ultraviolet detection (HPLC/UV) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for residues of dimethomorph in/on papaya.

V. Conclusion

Therefore, tolerances are established for residues of dimethomorph, in or on papaya at 1.5 ppm. While no pesticides containing dimethomorph have been registered in the United States for use on papaya, this tolerance allows importation of papaya containing permissible residues of dimethomorph under the FFDCA.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 9, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.493 alphabetically add the commodity "papaya" to the table in paragraph (a) to read as follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) *General*. * * *

Commodity	Parts per million
* * *	* * * *
Papaya[1]	1.5
* * *	* * * *

[1] There are no U.S. registrations as of January 20, 2015.

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[FR Doc. 2015-06106 Filed: 3/17/2015 08:45 am; Publication Date: 3/18/2015]